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EXAMINER				
LIPTIZ, JEFFREY BRIAN				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/535,617

Applicant(s)

BARTOLI, FRANCO

Examiner

JEFFREY B. LIPITZ

Art Unit

3769

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 20, 22-25, 27 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 20, 22-25, 27 and 29-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2010 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

This response is a reissue of the Final rejection, issued on December 23, 2009. Applicant's amendments and arguments submitted February 23, 2010 are also addressed in this office action.

Applicant's drawing amendments are acknowledged and have been considered. Figures 11, 12, 13a, 13b, and 18 are accepted, and thus the drawing objections withdrawn. However, Figures 2 and 14-17 are still not in acceptable condition. Figure 2 contains text which is not clear, and need not be unclear. The size and bolded of the text used is unacceptable. When this Application or patent is published, the text will not be understood. Figures 14-16 contain blurred images intended to illustrate where those image converges relative to the retina. In the last office action, Examiner thought those images were intended to be people. Every feature or element of a drawing should easily be able to be discerned. There is no need for these figures to contain blurred borders and features. These figures should be redrafted. Figure 17 is confusing in every respect. There are no labels indicating what the light and dark regions represent, nor is there any corresponding discussion of Figure 17 in the specification. All of the images are faded and fuzzy. The "Overall wavefront aberration" and "cylinder" images have partially shaded sections that also have no specified meaning. The drawing objections to Figures 2 and 14-17 have been maintained.

Applicant's arguments with respect to the 112 2nd Paragraph rejections filed February 23, 2010 have been fully considered but they are not persuasive.

Regarding claim 18, Applicant asserts that the conditional steps are manipulative because they are "part of the method that results in obtaining an overcorrect photoablative pattern inducing positive spherical aberration". However, Applicant does not state how they manipulate the step of obtaining or the step of controlling. If these conditional steps are part of the interpretation of the aberrometric map, then perhaps the step of interpreting should be further modified with this conditional language. Furthermore, the steps of interpreting the map and or the conditional steps are not currently linked to a device or element. Applicant probably intended to write that they are linked to the controller, but that is not necessarily the case. Although the interpretation of the map and the conditional steps may be implemented with a programmed controller, these computational steps could also be performed by hand (albeit laboriously). As currently written, these conditional steps do not manipulate the step inducing a spherical aberration because the absolute values of the "detected spherical aberration" are presumably the same. The 112 rejection of claim 18 is maintained.

Regarding claims 20 and 27, the conditional steps of claims 18 and 25 discuss the signs (in these instances negative) of these induced spherical aberrations. Increasing the absolute value of a negative (negative to begin with or sign was changed) spherical aberration inherently results in inducing a positive spherical aberration. Furthermore, as discussed in the previous office action, it appears that the method and apparatus of the present invention requires induction of a positive spherical aberration. How else can the method reduce presbyopia? These limitations appear to

be descriptive of the type of aberration induced to reduce presbyopia rather than identification of an additional step or element required for doing so. For all of these reasons, the 112 rejections of claims 20 and 27 are maintained.

Regarding claims 25, 27 and 29-30, Applicant asserts that the manner in which a control means is configured is not inherent. Examiner agrees; however, its configuration does not impose any structural limitations on the elements of the invention. Structural limitations should relate to the elements and features of a structure or the cooperation of those elements or features. Furthermore, Applicant provides no drawings of the control means (first or second), how they structurally relate to one another, and to the laser. Accordingly, a drawing objection has been added to this office action. A good way to think about Applicant's proposed system is that the limitations of claims 27, 29 and 30 do not add a new element or device to the system and they do not alter the structural relationship between the existing elements. The manner in which they functionally cooperate to bring about an intended outcome is applicable to the method, but the system must identify or modify physical features of the system. Therefore, the 112 rejection of claim 25 has been withdrawn, but the rejections of claims 27, 29 and 30 have been maintained.

Regarding claim 31, Applicant asserts that providing a second control means is possible, and therefore not indefinite. There are two problems with this line of reasoning. First, if Examiner does not understand the purpose of the elements recited, then those elements won't be permitted in the final draft of the patent. Second, merely reciting supposed structural correlatives to method claims is not the point of providing

structure claims. An apparatus should be claimed in conjunction with a method when the apparatus is *required* to perform the method. On the other hand, a method should be claimed in conjunction with an apparatus when the method is *required* to use the apparatus. If either the method can be carried out with another apparatus or the apparatus can be used to practice a different method, then the method and apparatus are distinct inventions. In the instant case, Applicant's claimed system is merely a reiteration of the steps of the method, and does not constitute a true system. Evidence for this assertion can be found in the lack of any drawings related to aberrometric measuring means, first and second photoablative pattern generating means, supply means and the structural cooperation between any of these elements. For instance, where is the first photoablative pattern generating means in relation to the second? What optical components enable the generation of different patterns? Since Applicant asserts that the first control means is distinct from the second, where is the first control means in relation to the second? Therefore, the 112 rejection of claim 31 has been maintained. Furthermore, in relation to the above discussion, additional written description rejection of claim 25 and drawing objections have been made.

Applicant's arguments with respect to the prior art rejections of the system have been considered but are not persuasive. Applicant asserts that Bille does not teach a control means that induces a fourth order aberration. However, Applicant fails to argue that Bille's system is not capable of performing such an aberration. The system of Applicant does not contain elements or structural cooperation that uniquely enable it to induce a fourth order aberration. Applicant's system simply contains a control means

capable of programming and an excimer laser. As discussed in relation to other rejections and objections, Applicant's disclosure does not describe or illustrate a system. Examiner has taken the position that Bille's system [and William's system] are capable of performing the method of claimed, whether or not there is suggestion to do so. The only reason Bille was used, rather than Williams, is because Examiner thought Bille's drawings and description of the system were clearer.

Applicant's arguments with respect to the method claims have been considered but are moot in view of the new grounds of rejection.

Applicant's arguments with respect to the finality of this action have been fully considered but they are not persuasive. Applicant asserts that Examiner cannot issue a final action when substantial amendments have been made, because the amendments did not require a further search; and therefore, Examiner should not introduce a new reference. This is false for several reasons. First of all, Examiner initially rejected claims in part because they were indefinite, and therefore, may have been unclear as to how to best apply the prior art. Following Applicant's amendments, these claims and became more clear and thus the best art for rejecting them was modified. Second of all, although new references were introduced, the same rejection based on the first references was also maintained. Third of all, the point of Examiner and Applicant's representatives' work is to uncover or clarify allowable subject matter. In so doing, Examiner will continue to introduce new references where appropriate to buffer arguments relating to allowable subject matter. This action is only being reissued because the statements relating to which claims were rejected did not match the claims

rejected in the body of the rejection. If this occurs in any subsequent actions, Applicant is advised to contact Examiner to clarify any discrepancies. Likewise, if anything is unclear in rejection, Applicant is advised to contact the Examiner. This action will be made final.

Drawings

The drawings are objected to because Figures 2 and 14-17 have no elements labeled and contain elements that are barely discernable. For instance, the image of the person in Figures 14-16 has no outline and blends in with the background. See the response to arguments section for a more detailed explanation.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the aberrometric measuring means, first and second photoablative pattern generating means, supply means and the structural cooperation between all of these elements must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Where is the first photoablative pattern generating means in relation to the second? What optical components enable the generation of different patterns? Since Applicant asserts that the first control means is distinct from the second, where is the first control means in relation to the second? The structural cooperation of all elements must be clearly described in the specification to enable one of ordinary skill in the art to make and use the invention. Merely stating how the control means is programmed does not constitute how the various elements interact and is not a substitute for a description of each element and its physical place within the system.

.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 20, 27, 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding all of these claims, see the "Response to arguments" section supra and the prior office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 27 and 29- 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Bille et al. (US Patent 6155684), hereinafter Bille.

Regarding claims 25 and 28, a "first control means for controlling laser", a "generating means" and "means for acquiring" are recited, which are all interpreted as invoking 35 U.S.C. 112, sixth paragraph as they include functional language and do not include sufficient structure for achieving the specified function.

Regarding claims 25, 27, 29 and 30, Bille teaches a control system for controlling an excimer laser, where the control unit uses a direct template of the target surface shape of the cornea to be obtained to control the amount of ablation to be accomplished in particular area (Column 5, Lines 38-52). The adaptive optical closed-loop system is

used to measure the spatially modified profile prior to the surgery, during and after it. Bille teaches providing an adaptive system specifically in order to measure higher order aberrations (Column 4, Lines 5-23). As an example, Figure 5 is a plot measuring spherical aberration as a function of focus. Examiner interprets the system as capable and moreover intended to treat astigmatic disorders, which includes presbyopia (Background of the Invention).

Bille teaches linking his diagnostic system to a laser control system (Column 5, Lines 38-50), his diagnostic system including a computer (22), which controls and records measurements of the second (myopia and hyperopia; Column 10, Lines 20-40) and fourth order (aberration) defects. These measurements are then used to generate a photoablative pattern. Examiner also directs Applicant's attention to the 112 2nd Paragraph rejections. These means for statements do not actually constitute new elements. A control system capable of transmitting ablative data and patterns to the laser is sufficient to accomplish these functions. The remaining limitations appear to be functional limitations that do not further modify the structure of the control system. These limitations receive negligible patentable weight.

Regarding claim 31, a "second means for controlling the excimer laser unit" is recited and interpreted as invoking 35 U.S.C. 112, sixth paragraph as it includes functional language and does not include sufficient structure for achieving the specified function. Bille teaches that a computer can use the acquire template or profile to control the amount of ablation (Column 5, Lines 43-45), thus suggesting a second control means or a second computer that directly controls the laser.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18, 20, 22, 24 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al. (6045578), hereinafter Collins in view of Bille.

Regarding claims 18, 20, 22, 24 and 32-34, Collins teaches inducing a positive spherical aberration in the myopic and hyperopic eye (Abstract). Although Collins does not mention presbyopia in particular, the inventive method of Collins is concerned with correcting or reducing spherical aberrations. Presbyopia results in myopic vision, and therefore its correction may be similar to that of myopia. Collins teaches treating a myopic condition by producing a positive spherical aberration (Column 4, Lines 16-30). Collins also suggests inducing this aberration by surgical alteration (Column 2, Lines 65-67). However, Collins does NOT teach using a laser to perform this surgical alteration.

Attention is directed to Bille who teaches the system described in claims 25, 27, 29, 30 and 31, rejected supra. It would have been obvious to use the system of Bille with the method of Collins because Bille's system is intended to be used to correct refractive aberrations of eye including myopia (Abstract and Background of the Invention).

Collins does also does NOT teach acquiring and interpreting an aberrometric map. Although measurement of the of higher order aberrations, such as spherical aberrations, would be inherent in any of Collin's methods of treatment, he does NOT discuss these measurements. Attention is again directed to Bille who teaches providing an adaptive system specifically in order to measure higher order aberrations (Column 4, Lines 5-23). It would have been obvious to measure and detect the defects of the eye before treating it, because appropriate treatments are always based directly on measured defects. A method that did not include measuring the defects could result in an improper ablation of the eye, and probably additional optical complications.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collins and Bille as applied to claims 18 and 22 in view of[C. E. Martinez et al, "Changes in corneal aberration structure after photorefractive keratectomy."

Regarding claim 23, William does NOT teach ablation with a customized ablative pattern to obtain even greater spherical aberration with a coefficient of Zernike's polynomial Z_4^0 . However, Martinez et al. teaches that spherical aberration is highly correlated with best spherical-correlated visual acuity in normal eyes and results show for 4th order aberration postoperative surgery, the Zernike coefficient for 60 patients with 7-mm pupil diameters equals 0.9999 (Table 5; par. 9, lines 3 & 4) and fourth-order Zernike coefficients Z11 through Z15 are indicators of spherical-like aberration. When values were calculated for a 3-mm pupil (Table 3), Z-, Z-2, and Z-4 had changed by 1 month after surgery and never returned to preoperative values. In the 7-mm pupil calculations (Table 4), coefficients Z1- and Z-4 had changed by 1 month after surgery

(P.001) (par. 27 [Zemike Coefficients]), wherein patient's eyes are observed in location with dim lighting, causing the pupil to dilate.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the positive spherical aberration of William et al. by modifying the Zernike coefficient to equal 0.999 as taught by Martinez, therefore reducing the effects of presbyopia in the 4th order. The examiner interprets the claims as written in a conditional format, therefore only one "if" condition for each claim needs to be met.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY B. LIPITZ whose telephone number is (571)270-5612. The examiner can normally be reached on Monday to Thursday, 10 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry M. Johnson III can be reached on (571)272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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